Middle ear vibrations with SMA prosthesis. Experimental research

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Abstract. The paper focuses on experimental research of a middle ear prosthesis made of shape memory alloy. The prosthesis provides better adjustment to individual patient than classical prosthesis. The shape memory prosthesis is implemented to a fresh temporal bone and vibrations of the round window are recorded by means of the Laser Doppler Vibrometer. Finally, the results are presented in the form of transfer function and compared to the intact and damaged middle ear.

1 Introduction

The human middle ear forms a sound conduction system that transmits sound from the external ear to the fluids of the inner ear through three ossicles: the malleus, the incus, and the stapes. The ossicles are connected to each other by the incudo-mallear and incudo-stapedial joints. The whole ossicular chain is supported by the tensor tympani muscle and the stapedius muscle to the temporal bone. The malleus is also firmly connected to the tympanic membrane, whereas the stapes is attached to the bony walls of the oval window by an annular ligament forming a stapediovestibular junction.

The ossicular chain can be destroyed by inflammatory diseases such as chronic suppurative otitis media or cholesteatoma. For patients with middle ear dysfunctions, the medical practice called ossiculoplasty (reconstruction of the middle ear ossicles) can improve the hearing process. This technique has been used in clinical practice for over 50 years. Various procedures are currently used, and a variety of middle ear prostheses are available. The classical TORP (Total Ossicular Replacement Prosthesis) and PORP (Partial Ossicular Replacement Prosthesis) are made of various materials with titanium or titanium alloy being most frequently used. They connect the tympanic membrane or the malleus to the stapes head or stapes footplate. Results of the middle ear reconstruction are presented in many medical papers [1–12]. Meulemans et.al. [13] have tested titanium Kurz variac PORP. All patients have underwent a pure-tone audiometry hearing test that has determined pure-tone thresholds in the frequency range from 250 to 4000 Hz by air and bone conduction. Pure tone audiograms have been also performed after surgery reconstruction made by classical titanium prosthesis in [8], to estimate effects of different ossiculoplasty materials in [14] and to test the active middle ear implant [15]. Bony ankylosis hydroxyapatite prostheses in the middle ear have been presented in [11] but without any experimental verification.

Audiometry is relatively simple and therefore quite common technique, however in most cases more precisely the Laser Doppler Vibrometer (LDV) is used to measure ossicular vibrations of the middle ear. LDV is applied to measure motion of the intact ossicular chain [16], tympanic membrane [17] and the reconstructed middle ear [18, 19]. The reconstruction by means of adjustable-length titanium prosthesis is presented in [20], optimal tension for PORP is discussed in [7]. The effects of vibration transmission to the footplate of inserting cartilage of varying sizes, and materials of varying rigidities is examined in [12].

Most of the presented prostheses cannot be modified after they have been prepared. If a prosthesis is too short, it must be lost. Prostheses length can be chosen only once before surgery. Sometimes, a reduction of the prosthesis length [20] and head plate area is possible by breaking some rings of the head plate. Therefore, here a new idea of the prosthesis made of Nitinol or Flexinol is presented. In the literature, the prostheses made of Nitinol are known as the piston–stapes prosthesis (NiTiBOND), and self-crimping prostheses [21, 22]. However, to the authors' knowledge, no study has considered the problems of shape memory prostheses (SMP) which are able to adjust their length to individual patient's need.

The main goal of this research is to test experimentally the handmade shape memory prosthesis (SMP) in the human middle ear. The idea of the SMP is reported in previous papers where the static model of C-shape SMP [23] and dynamical behaviour of the middle ear with SMP [24] is analysed. The paper is organized as follows: the section two presents an experimental procedure, bone prepa-

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ration and testing setup. The section three shows results of measurements in the form of transfer function. Finally, discussion and closing remarks are collected in the section four.

2 Experimental procedure

Vibrations of the round window (RW) are measured on the fresh human temporal bone specimen (figure 1) by means of the Laser Doppler Vibrometer (LDV) in case of the intact, damaged and reconstructed middle ear (ME). Firstly, the human temporal bone and the shape memory prosthesis (SMP) have been prepared as it is described in sections 2.1 and 2.2. Next, the middle ear is stimulated by sound in the range of 0.2 to 8 kHz and motion of RW has been recorded in the following cases:

- intact middle ear (IME)
- middle ear without the incus (damaged middle ear - DME)
- reconstructed middle ear with the help of the SMP

First, measurements have been taken from the intact middle ear to obtain a baseline for the RW vibration. Next, the incus has been removed to simulate a damaged ear and to be able to reconstruct ME with the help of the shape memory prosthesis. The results of experiment are presented as the transfer function between the RW velocity and the sound pressure applied to the ear.

2.1 Bone preparation

The fresh human temporal bone has been prepared to the experiment (figure 1). Firstly, the soft tissue has been removed and a standard antromastoidectomy with posterior tympanotomy performed. The mastoid facial nerve has been removed to visualize the stapes arch and the footplate. An artificial external ear canal of length 25 mm and diameter 9 mm was then attached to the bone with epoxy resin. The artificial canal is equipped with two ports, one for an ear microphone (ER-7C Etymotic Research) and one for a sound source (ER2 Etymotic Research). The artificial canal was closed with the glass plate to create a sound sealed chamber. Pieces of reflective tape (weighing less than 0.05 mg) were placed over the round window membrane. The temporal bone specimen was then embedded in dental cement and put in the temporal bone holder (Storz).

2.2 Shape memory prosthesis

The shape memory prosthesis consists of two parts. The main part is a stick made of Flexinol and a holder made of titanium. The stick diameter is 0.2mm. An activation temperature of the Flexinol is 70^{o}C. The prototype of the SMP is shown in figure 2. Initially, the SMP (stick) curved to be shorter in order to implement easier in the middle ear (figure 2a), next after heating the SMP gets longer and takes the shape presented in figure 2b. More details cannot be published because the SMP project is applied to Polish Patent Office and it is still under consideration.

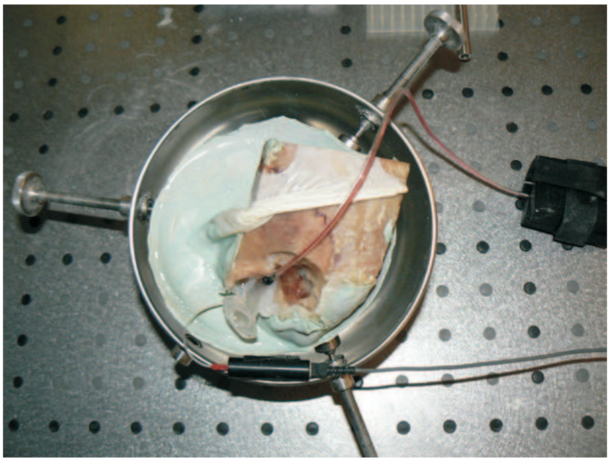

Figure 1. Temporal bone prepared for measurements with the microphone and the sound source

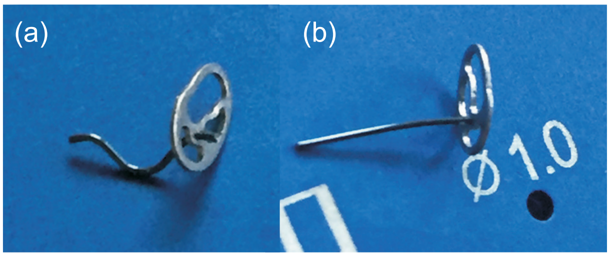

Figure 2. Handmade shape memory prosthesis, (a) before heating, (b) after heating

2.3 Testing setup

The measurements of the RW motion have been performed on the antivibration table inside the sound booth (figure 3a). The sound stimuli has been frequency sweeps from 0.2 - 8kHz. The frequency range is important for speech recognition, therefore this range is analysed in the paper. Indeed, a one - point modal analysis is performed here because the sweep signal is an excitation and the output signal (velocity) is measured. The sound source has been connected to a power amplifier (AP-12) to produce an adequate signal output. The round window velocity has been measured with the Polytec Laser Doppler Vibrometer system (figure 4) composed of an OFV-5000 controller with VD-06 velocity decoder and an OFV-534 laser head. The head has been connected to a joystick-operated micromanipulator, which is mounted on the microscope. Using the micromanipulator, the helium-neon laser beam has been directed onto retroreflective targets on the RW through the artificial ear canal. The real view and the scheme of the experimental setup is presented in figure 3 and 4. Velocity of the RW has been analysed and acquired by means of The LMS Scadas Mobile operated by TestXpress software.

3 Middle ear vibration

Vibration of the round window is presented as the transfer function in decybel scale in figure 5. The intact middle ear

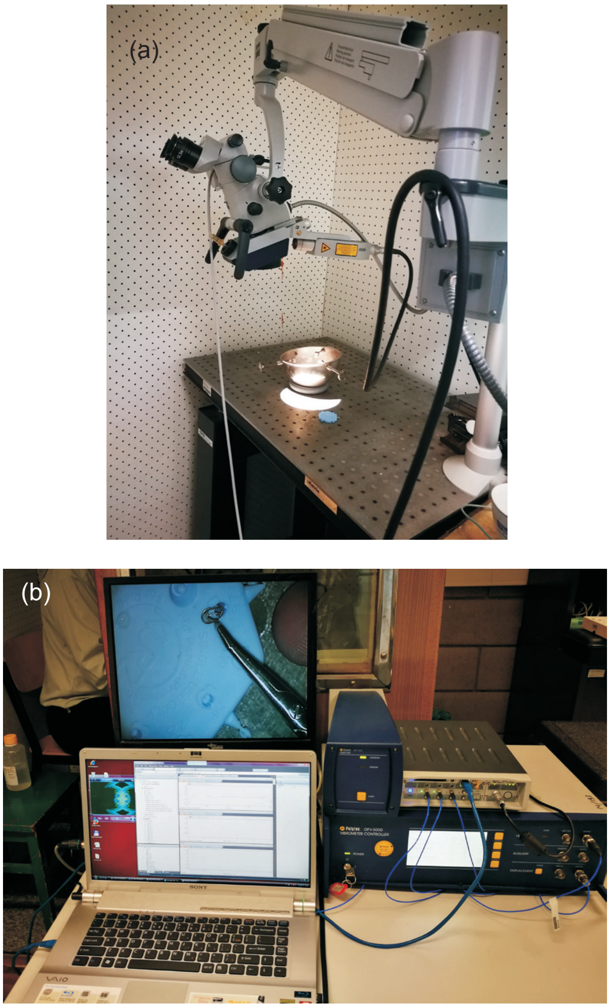

Figure 3. Real view of experimental standing for middle ear vibrations, (a) the sound booth with the laser head, the microscope and the antivibration table, (b) the measuring setup

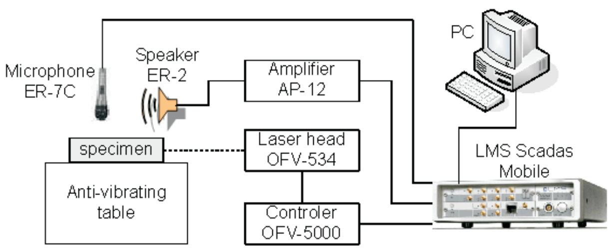

Figure 4. Scheme of experimental standing for middle ear vibrations

(IME) is the base line with two characteristic picks at 1kHz and 5kHz. These are the natural frequencies of a human middle ear. When the incus is removed the sound transmission process is perturbed and consequently the damaged middle ear (DME) line is below the base line (IME), according to our expectation. Hearing loss is about 20dB. Moreover, the natural frequencies are shifted left. After middle ear reconstruction with the help of the shape memory prosthesis natural frequencies are almost the same as in the intact middle ear (IME) and hearing loss is only

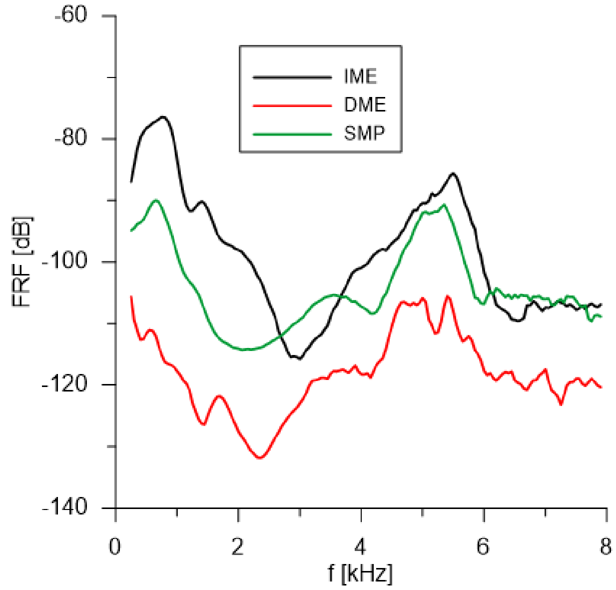

Figure 5. Vibration of round window for intact middle ear (IMR), damaged middle ear (DME) and reconstructed by means of shape memory prosthesis (SMP)

about 5dB at 5kHz and 15dB at 1kHz. Of course, any prostheses (reconstructed middle ear) cannot be as good as the intact ear. Note, that possibility of easier implementation is the most important advantage of the shape memory prosthesis.

4 Conclusions

From theoretical point of view the idea of shape memory prosthesis is presented in [23, 24]. The successful theoretical consideration are confronted here with the experimental test. The shape memory prosthesis of the human middle ear improves hearing compared to the damaged ear but we should remember that possibility of easier implementation is the most important advantage of the shape memory prosthesis. In the next step, the results of the sound transmission through reconstructed middle ear with the use of the shape memory prosthesis will be compared to classical prostheses available commercially.

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